510(k) Summary

JUN 0 7 2013

Date: May 15, 2013

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
Cheryl Hastings
Principal Consultant
Phone: 574-527-4220
FAX: +39 0432945512

Product	Common Name	Product Code	Regulation and Classification Name
SMR CTA Humeral Heads	Total or Hemi Shoulder Prosthesis	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660
		HSD	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis per 21 CFR 888.3690

Description:

The SMR CTA Humeral Heads (cleared via 510(k): K110847) are intended for use with a humeral body – humeral stem assembly in total or hemi-shoulder joint arthroplasty. The CTA heads are coupled with the humeral bodies by means of an adaptor taper. When used in total shoulder replacement, the SMR CTA Humeral Heads are coupled with glenoid components.

The SMR CTA Humeral Heads were cleared in K110847 for use with the humeral stems, humeral bodies, adaptor tapers and glenoid components cleared in K100858, K101263 and K113254.

This submission is to modify the labeling for the SMR CTA Humeral Heads to add the SMR Reverse Humeral Bodies, cleared via K110598, as additional compatible components. An adaptor for the reverse humeral body is being added to allow coupling between the SMR CTA Humeral Heads and the SMR Reverse humeral body. When used with the CTA Humeral Heads, the SMR Reverse Humeral Bodies are intended for anatomic shoulder replacement.

Intended Use / Indications:

The SMR CTA Humeral Heads are intended for use with cemented and uncemented SMR humeral body – humeral stem assemblies in total or hemi- shoulder joint arthroplasty. The glenoid is intended for cemented use only. Total and hemi-shoulder replacement utilizing the CTA head is indicated for patients suffering from disability due to:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- Cuff tear arthropathy.

Predicate Device:

Limacorporate SMR CTA Humeral Heads (K110847)
Limacorporate SMR Reverse Shoulder System (K110598)

Summary of Technologies/Substantial Equivalence:

Based on similarities in indications, intended use, design, materials, surface finishing, method of manufacture and a print review to compare taper dimensions and tolerances, Limacorporate believes that the SMR CTA Humeral Heads with modified labeling to include the SMR Reverse Humeral Bodies as compatible components are substantially equivalent to the SMR CTA Humeral Heads cleared in K110847.

Non-Clinical Testing:

A print review was conducted to compare the taper dimensions and tolerances of the adaptor used for coupling the SMR CTA Humeral Heads to the SMR Reverse Humeral Bodies with the taper coupling for the SMR reverse humeral bodies and liners cleared via K110598 and with the taper coupling for the SMR CTA Humeral Heads and adaptors cleared via K110847. These comparisons indicate that the adaptor tapers for the coupling of the reverse humeral bodies and the CTA heads is equivalent in dimensions and tolerances to the predicates. A review of previously conducted fretting / corrosion testing also indicates that the SMR CTA Humeral Head / SMR Reverse Humeral Body adaptor does not introduce new risks of fretting or corrosion.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the SMR CTA Humeral Heads with modified labeling to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 7, 2013

Limacorporate S.p.A.
% Ms. Cheryl Hastings
Principal Consultant
P.O. Box 696
Winona Lake, Indiana 46590-0696

Re: K131112
Trade/Device Name: SMR CTA Humeral Heads
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: May 3, 2013
Received: May 10, 2013

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131112

SMR CTA Humeral Heads
Indications for Use

The SMR CTA Humeral Heads are intended for use with cemented and uncemented SMR humeral body – humeral stem assemblies in total or hemi- shoulder joint arthroplasty. The glenoid is intended for cemented use only. Total and hemi-shoulder replacement utilizing the CTA head is indicated for patients suffering from disability due to:

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- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- Cuff tear arthropathy.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices